



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 16 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Aloka Co., Ltd.  
% Mr. Daniel W. Lehtonen  
Responsible Third Party Official  
Intertek Testing Services NA, Inc.  
70 Codman Hill Road  
BOXBOROUGH MA 01719

Re: K060059

Trade Name: Aloka SSD-3500 Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulation Number: 21 CFR 892.1570  
Regulation Name: Diagnostic ultrasonic transducer  
Regulatory Class: II  
Product Code: IYN, IYO, and ITX  
Dated: January 6, 2006  
Received: January 9, 2006

Dear Mr. Lehtonen:

This letter corrects our substantially equivalent letter of January 13, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aloka SD-3500 Ultrasound System, as described in your premarket notification:



*Protecting and Promoting Public Health*

Transducer Model Number

UST-536  
UST-672-5/7.5 (C) / (L)  
UST-676P  
UST-677P (L) / (T)  
UST-978-3.5  
UST-984-5  
UST-990-5  
ASU-1003  
ASU-1009  
UST-5293-5  
UST-5298  
UST-5299  
UST-5524-7.5  
UST-5542

UST-5546  
UST-5548  
UST-5710-7.5  
UST-9101-7.5  
UST-9102-3.5  
UST-9102(U)-3.5  
UST-9104-5  
UST-9112-5  
UST-9121  
UST-9123  
UST-9124  
UST-9127  
UST-9128  
UST-9133

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

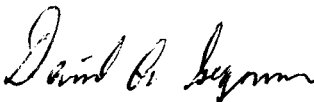
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

  
for

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

K060059

Aloka Co., Ltd.

Model SSD-3500

510(K)

Date: 10/17/05

JAN 13 2006

**510(k) Summary: Aloka Model SSD-3500 Ver. 7.0 Diagnostic Ultrasound System**

This summary statement complies with 21 CFR, section 807.92 as amended March 14, 1995.

This premarket notification has been submitted by Aloka Co., Ltd. and covers the Aloka SSD-3500 Ver. 7.0 diagnostic ultrasound system and transducers. The address is:

10 Fairfield Boulevard  
Wallingford, CT 06492  
Tel: (203) 269-5088  
Fax: 203-269-6075

The contact person is: Richard J.Cehovsky, RA/QA Coordinator

The proprietary name is the Aloka SSD-3500 Ver. 7.0 diagnostic ultrasound system and transducers. The common name for this type of device is a diagnostic ultrasound system and transducers.

The item in this submission is covered under the following classification:

90 IYN	Ultrasonic Pulsed Doppler Imaging System	21 CFR 892.1550
90 ITX	Diagnostic Ultrasound Transducer	21 CFR 892.1570
90 IYO	Ultrasonic Pulsed Echo Imaging System.	21 CFR 892.1560

The above as stated in 21 CFR, part 892.1570, 1560 and 1550, has been classified as regulatory Class II.

The Aloka SSD-3500 Ver. 7.0 and its transducers are substantially equivalent to its predicate; the Aloka SSD-3500 Ver. 1.0 and its transducers.

The Aloka SSD-3500 Ver. 7.0 functions in the same manner as other diagnostic ultrasound devices and its predicate. High frequency sound waves are transmitted into the body by a piezo-electric transducer. In the body, differences in the acoustic impedance of different tissues reflect a certain amount of the ultrasound energy back to the transducer, where it is transmitted via the probe cable to the system console and processed into an image. The Aloka SSD-3500 Ver. 7.0 transducers can also use the Doppler shift of sound reflected from moving tissues (blood) to detect and display flow.

The Aloka SSD-3500 Ver. 7.0, like other Aloka marketed diagnostic ultrasound systems and transducers is indicated for imaging body structures to aid in the diagnosis of disease or abnormality.

The Aloka SSD-3500 Ver. 7.0 diagnostic ultrasound system and transducers are similar in technological characteristics to Aloka's predicate ultrasound system: SSD-3500 Ver. 1.0 (K023996).

- The SSD-3500 Ver. 7.0 is indicated for the same diagnostic ultrasound applications to Aloka's ultrasound system: SSD-3500 Ver. 1.0 (K023996).

**510(k) Summary: Aloka Model SSD-3500 Diagnostic Ultrasound System**

- The SSD-3500 Ver. 7.0 has the same gray-scale and Doppler abilities to Aloka's ultrasound system: SSD-3500 Ver. 1.0 (K023996) .
- The SSD-3500 Ver. 7.0 uses essentially the same technologies for imaging, Doppler functions and signal processing as the following product currently marketed by Aloka : SSD-3500 Ver. 1.0 - (K023996).
- The SSD-3500 Ver. 7.0 has the same method of use as the following products currently marketed by Aloka: SSD-3500 - (K023996).
- The SSD-3500 acoustic power output levels are below the maximum levels allowed by the FDA.
- The SSD-3500 is subjected to the same Quality Assurance systems in development and production as other products currently marketed by Aloka such as the: SSD-3500 - (K023996).
- The patient contact materials used in the SSD-3500 Ver. 7.0 have been evaluated for safety via the same standards and methods as the above mentioned products marketed by Aloka. These materials have been found to be safe for the intended uses.
- The SSD-3500 Ver. 7.0 complies with electrical and physical safety standards as other products currently marketed by Aloka such as its predicate: SSD-3500 - (K023996).
- Aloka Co., Ltd. Certifies that the SSD-3500 Ver. 7.0 complies with NEMA-UD2:2004 Rev. 3- (Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment), NEMA-UD3: 2004 Rev.2- ( Standard for Real Time Display of Thermal & Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment), and IEC-60601-1-2: 2001 – ( Medical Electrical Equipment Part 1-2: General requirements for Safety-Collateral standard: Electromagnetic compatibility-Requirements and Tests).

## 4.3.1

**Diagnostic Ultrasound Indications for Use Form**  
SSD-3500

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P		P	P		See Below	
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)		P	P	P		P	P		See Below	
Intraoperative Neurological		P	P	P		P	P		See Below	
Pediatric		P	P	P		P	P		See Below	
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic		P	P	P		P	P		See Below	
Adult Cephalic		P	P	P		P	P		See Below	
Cardiac		P	P	P		P	P		See Below	
Transesophageal		P	P	P		P	P		See Below	
Transrectal		P	P	P		P	P		See Below	
Transvaginal		P	P	P		P	P		See Below	
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		See Below	
Laparoscopic		P	P	P		P	P		See Below	
Musculo-skeletal Conventional		P	P	P		P	P		See Below	
Musculo-skeletal Superficial		P	P	P		P	P		See Below	
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD

Intraoperative applications: include liver, pancreas and gall bladder. Small parts applications include breast, testes and thyroid.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

## Diagnostic Ultrasound Indications for Use Form

UST-536

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		N	N	N		N	N		See Below	
Intraoperative Neurological										
Pediatric		N	N	N		N	N		See Below	
Small Organ (specify)		N	N	N		N	N		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Intra-operative: liver, pancreas &amp; gall bladder, Small parts: breast, testes &amp; thyroid.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Ferguson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K060059

**Diagnostic Ultrasound Indications for Use Form**  
**UST-672-5/7.5 (C) / (L)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P		P	P		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P		See Below	
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

Intra-operative applications: Liver, pancreas and gall bladder

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Ferguson*  
 (Division Sign-Off)

Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number



**Diagnostic Ultrasound Indications for Use Form**  
UST-676P

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P		See Below	
Transvaginal		P	P	P		P	P		See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

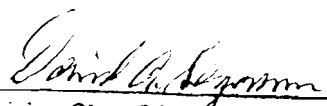
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K060005 G

## Diagnostic Ultrasound Indications for Use Form

UST-677P (L) / (T)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		N	N	N		N	N		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		See Below	
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

Intra-operative applications: Liver, pancreas and gall bladder

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David B. Segman*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 1460659

**Diagnostic Ultrasound Indications for Use Form**  
UST-978-3.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Lejars*  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number 206005

**Diagnostic Ultrasound Indications for Use Form**  
UST-984-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		P	P	P		P	P		See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

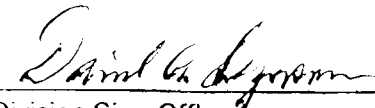
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 2060059

**Diagnostic Ultrasound Indications for Use Form**  
UST-990-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P		P	P		See Below	
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David R. Ingram*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number ✓ 1060059

**Diagnostic Ultrasound Indications for Use Form**  
ASU-1003

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P		P	P		See Below	
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		P	P	P		P	P		See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Leggett*  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number 7660059

**Diagnostic Ultrasound Indications for Use Form**  
ASU-1009

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		N	N	N		N	N		See Below	
Abdominal		N	N	N		N	N		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Leggett*  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

**Diagnostic Ultrasound Indications for Use Form**  
UST-5293 -5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P		P	P		See Below	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Heyman*  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number



**Diagnostic Ultrasound Indications for Use Form**  
UST-5298

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Optthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P		P	P		See Below	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

**Diagnostic Ultrasound Indications for Use Form**  
UST-5299

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P		P	P		See Below	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*Christina E. Egan*  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

*2060059*

**Diagnostic Ultrasound Indications for Use Form**  
UST-5524-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

Small parts application includes: breast, testes and thyroid

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

MDR Number

**Diagnostic Ultrasound Indications for Use Form**  
UST-5542

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

Small parts application includes: breast, testes and thyroid

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David G. DeGroom*  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

**Diagnostic Ultrasound Indications for Use Form**  
UST-5546

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

Small parts application includes: breast, testes and thyroid

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Ferguson*  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

## Diagnostic Ultrasound Indications for Use Form

UST-5548

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

Small parts application includes: breast, testes and thyroid

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Ferguson*

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

*1060059*

**Diagnostic Ultrasound Indications for Use Form**  
UST-5710-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

Small parts application includes: breast, testes and thyroid

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David R. Lippman*  
(Division Sign-Off)

Division of Reproductive, Abdominal  
and Radiological Devices

*K06005*

**Diagnostic Ultrasound Indications for Use Form**  
UST-9101-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David M. Larson*  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

2060059



## Diagnostic Ultrasound Indications for Use Form

UST-9102-3.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

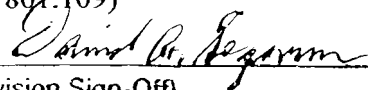
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number



**Diagnostic Ultrasound Indications for Use Form**  
UST-9102(U)-3.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Ferguson*  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
610(k) Number 106005

## Diagnostic Ultrasound Indications for Use Form

UST-9104-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P		P	P		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic		P	P	P		P	P		See Below	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

Intra-operative applications: Liver, pancreas and gall bladder

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices  
Product Number

## Diagnostic Ultrasound Indications for Use Form

UST-9112-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P		P	P		See Below	
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		P	P	P		P	P		See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Legroom*  
 Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number: 80100059

**Diagnostic Ultrasound Indications for Use Form**  
UST-9121

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

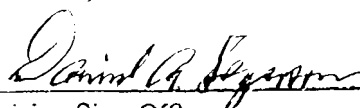
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 206005

**Diagnostic Ultrasound Indications for Use Form**  
UST-9123

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P		P	P		See Below	
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										


N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 File Number 2060059

Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal									
Transvaginal		P	P	P		P	P		See Below
Transurethral									
Intravascular									
Peripheral Vascular									
Laparoscopic									
Musculo-skeletal Conventional									
Musculo-skeletal Superficial									
Other									

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Lyson*

(Signature Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
Device Number

106005

## Diagnostic Ultrasound Indications for Use Form

UST-9127

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		N	N	N		N	N		See Below	
Abdominal		N	N	N		N	N		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Legram*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 2000059



## Diagnostic Ultrasound Indications for Use Form

UST-9128

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P		P	P		See Below	
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Leggett*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 NDA Number KL00059

Intraoperative (specify)		N	N	N		N	N		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD.

Intra-operative applications: Liver, pancreas and gall bladder

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David W. Seymour*

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

Device Number